510(k) SUMMARY

SUBMITTER:	Sorin Group Italia 86, Via Statale 12 Nord 41037 Mirandola (MO) Italy
CONTACT PERSON:	Luigi Vecchi Phone: 39 0535 29811 Fax: 39 0535 25229
DATE PREPARED:	September 22, 2011
DEVICE TRADE NAME:	BMR1900 PH.I.S.I.O.
COMMON NAME:	Closed Venous Reservoir Bag
CLASSIFICATION NAME:	Reservoir, Blood, Cardiopulmonary Bypass
UNMODIFIED DEVICES:	SMARxT BMR1900 Closed Venous Reservoir Bag (K050111)

DEVICE DESCRIPTION:

The BMR1900 PH.I.S.I.O. is a sterile, non-pyrogenic softshell reservoir designed for use in cardiac surgical procedures requiring extracorporeal support for periods of up to six hours.
The BMR1900 PH.I.S.I.O. can be operated at flow rates up to 6 liters per minute. The maximum operating volume is 1900 mL. The minimum operating volume is 300 mL.
The softshell reservoir has a blood inlet port with an integral cardiotomy inlet on one side of the bag and a blood outlet port on the opposite side of the bag with respect to the vertical axis.
Integral to the blood inlet port are connectors for measuring the temperature and saturation/hematocrit of the incoming blood using external monitoring equipment.
At the top edge of the bag it is located a dual four-way stopcock assembly that is used to manually purge air from the bag. The stopcock assembly may also be used for the administration of drugs or other solutions, as needed during the cardiopulmonary bypass procedure.
Blood enters the bag through the inlet port and passes through a polyester filter screen before exiting the bag through the outlet port. The purpose of the filter is to facilitate the removal of large air bubbles from the blood.

The BMR1900 PH.I.S.I.O. is a modified version of the currently marketed SMARxT BMR1900 Closed Venous Reservoir Bag.

INDICATION FOR USE:

The BMR1900 PH.I.S.I.O. is intended to be used in cardiac surgical procedures requiring extracorporeal support for periods of up to six hours.

No change to the intended use has been made as a result of the modifications.

TECHNOLOGICAL CHARACTERISTICS:

The BMR1900 PH.I.S.I.O. has the same technological characteristics, principles of operation and control mechanisms as the unmodified device. The fundamental scientific technology is unchanged.

The blood contact surfaces are treated with a phosphorylcholine (PH.I.S.I.O.) coating rather than SMARxT as for the unmodified device. Both PH.I.S.I.O. and SMARxT treatments improve blood compatibility of the device and have the same claim of reduced platelet adhesion.

Instructions for use and labeling have been revised to reflect the change from a SMARxT to a PH.I.S.I.O. treatment.

The BMR1900 PH.I.S.I.O. is ethylene oxide sterilized and has a non-pyrogenic fluid path. It is for single use only.

NON CLINICAL TEST RESULTS:

Applicable tests were carried out in accordance with the requirements of ISO 10993-1 and the FDA May 1st, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of materials.

IN VITRO TEST RESULTS:

In vitro testing was carried out to demonstrate both the substantial equivalence with the unmodified device and also to comply with safety and effectiveness requirements. The tests were performed according to internal methods developed by the Manufacturer using sterilized devices aged up to 3 years.

Comparative testing was performed to demonstrate equivalent performance of the BMR 1900 PH.I.S.I.O and the SMARxT BMR1900.

CONCLUSIONS:

The BMR1900 PH.I.S.I.O. has the same intended use, principles of operation and technological characteristics as the unmodified device. The testing performed demonstrates that the BMR1900 PH.I.S.I.O. is substantially equivalent to the SMARxT BMR1900.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

OCT 14 2011

Sorin Group USA, Inc.
c/o Mr. Scott Light
Regulatory Affairs Manager
14401 W. 65th Way
Arvada, CO 80004

Re: K112771
Trade/Device Name: BMR 1900 Ph.I.S.I.O.
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary bypass blood reservoir
Regulatory Class: Class II
Product Code: DTN
Dated: September 22, 2011
Received: September 23, 2011

Dear Mr. Light:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K112771

Device Name: BMR1900 PH.I.S.I.O.
Indication for Use:

The BMR1900 PH.I.S.I.O. is intended to be used in cardiac surgical procedures requiring extracorporeal support for periods of up to six hours.

Prescription Use___X____
(Part 21CFR 801 Subpart D)

Over-the- Counter Use_____
AND/OR (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112771